IC 16-42-22

Chapter 22. Drugs: Generic Drugs

IC 16-42-22-1

"Brand name" defined

Sec. 1. As used in this chapter, "brand name" means the proprietary or trade name selected by the drug manufacturer and placed upon a drug or the drug's container, label, or wrappings at the time of packaging.

As added by P.L.2-1993, SEC.25.

IC 16-42-22-2 Repealed

(*Repealed by P.L.239-1999, SEC.9.)*

IC 16-42-22-3

"Customer" defined

Sec. 3. As used in this chapter, "customer" means the individual for whom a prescription is written or electronically transmitted or the individual's representative.

As added by P.L.2-1993, SEC.25. Amended by P.L.204-2005, SEC.8.

IC 16-42-22-4

"Generically equivalent drug product" defined

Sec. 4. (a) As used in this chapter, "generically equivalent drug product" means a multiple source drug product:

(1) that contains an identical quantity of identical active ingredients in the identical dosage forms (but not necessarily containing the same inactive ingredients) that meet the identical physical and chemical standards in The United States Pharmacopeia (USP) described in IC 16-42-19-2, or its supplements, as the prescribed brand name drug; and

(2) if applicable, for which the manufacturer or distributor holds either an approved new drug application or an approved abbreviated new drug application unless other approval by law or of the federal Food and Drug Administration is required.

(b) A drug does not constitute a generically equivalent drug product if it is listed by the federal Food and Drug Administration on or after July 1, 1987, as having actual or potential bioequivalence problems.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.4.

IC 16-42-22-4.5

"Practitioner" defined

Sec. 4.5. As used in this chapter, "practitioner" means any of the following:

(1) A licensed physician.

(2) A dentist licensed to practice dentistry in Indiana.

(3) A podiatrist licensed to practice podiatric medicine in Indiana.

(4) An optometrist who is:

(A) licensed to practice optometry in Indiana; and

(B) certified under IC 25-24-3.

(5) An advanced practice nurse licensed and granted the authority to prescribe legend drugs under IC 25-23.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.5; P.L.157-2006, SEC.8.

IC 16-42-22-5

"Substitute" defined

Sec. 5. As used in this chapter, "substitute" means to dispense a generically equivalent drug product in place of the brand name drug product prescribed by the practitioner.

As added by P.L.2-1993, SEC.25.

IC 16-42-22-5.5

Limitation of effect of chapter

Sec. 5.5. Nothing in this chapter authorizes any substitution other than substitution of a generically equivalent drug product.

As added by P.L.239-1999, SEC.6.

IC 16-42-22-6

Prescription forms

Sec. 6. (a) Each written prescription issued by a practitioner must have two (2) signature lines printed at the bottom of the prescription form, one (1) of which must be signed by the practitioner for the prescription to be valid. Under the blank line on the left side of the form must be printed the words "Dispense as written.". Under the blank line on the right side of the form must be printed the words "May substitute.".

(b) Each electronically transmitted prescription issued by a practitioner must:

(1) have an electronic signature; and

(2) include the electronically transmitted instructions "Dispense as written." or "May substitute.".

As added by P.L.2-1993, SEC.25. Amended by P.L.204-2005, SEC.9.

IC 16-42-22-7 Repealed

(*Repealed by P.L.239-1999, SEC.9.)*

IC 16-42-22-8

Requirements for substitution

Sec. 8. (a) For substitution to occur for a prescription other than a prescription filled under the Medicaid program (42 U.S.C. 1396 et seq.), the children's health insurance program established under IC 12-17.6-2, or the Medicare program (42 U.S.C. 1395 et seq.):

(1) the practitioner must:

(A) sign on the line under which the words "May substitute" appear; or

(B) for an electronically transmitted prescription, electronically transmit the instruction "May substitute."; and

(2) the pharmacist must inform the customer of the substitution.

(b) This section does not authorize any substitution other than substitution of a generically equivalent drug product.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.7; P.L.291-2001, SEC.233; P.L.204-2005, SEC.10.

IC 16-42-22-9

Transmission of practitioner's instructions to pharmacist

Sec. 9. If the practitioner communicates instructions to the pharmacist orally or electronically, the pharmacist shall:

(1) indicate the instructions in the pharmacist's own handwriting on the written copy of the prescription order; or

(2) record the electronically transmitted instructions in an electronic format.

As added by P.L.2-1993, SEC.25. Amended by P.L.204-2005, SEC.11.

IC 16-42-22-10

Substitution prohibited

Sec. 10. (a) If a prescription is filled under the Medicaid program (42 U.S.C. 1396 et seq.), the children's health insurance program established under IC 12-17.6-2, or the Medicare program (42 U.S.C. 1395 et seq.), the pharmacist shall substitute a generically equivalent drug product and inform the customer of the substitution if the substitution would result in a lower price unless:

(1) the words "Brand Medically Necessary" are:

(A) written in the practitioner's own writing on the form; or

(B) electronically transmitted with an electronically transmitted prescription; or

(2) the practitioner has indicated that the pharmacist may not substitute a generically equivalent drug product by:

(A) orally stating that a substitution is not permitted; or

(B) for an electronically transmitted prescription, indicating with the electronic prescription that a substitution is not permitted.

(b) If a practitioner orally states that a generically equivalent drug product may not be substituted, the practitioner must subsequently forward to the pharmacist a written or electronically transmitted prescription with the "Brand Medically Necessary" instruction appropriately indicated in the physician's own handwriting.

(c) This section does not authorize any substitution other than substitution of a generically equivalent drug product.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.8; P.L.291-2001, SEC.234; P.L.204-2005, SEC.12.

IC 16-42-22-11

Substitution of generic drugs; identification of brand name drug

Sec. 11. If under this section a pharmacist substitutes a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label must identify the brand

name drug for which the substitution is made and the generic drug. The identification required under this subsection must take the form of the following statement on the drug container label, with the generic name and the brand name inserted on the blank lines:

"_____ Generic for _____".

As added by P.L.2-1993, SEC.25. Amended by P.L.186-1993, SEC.1.

IC 16-42-22-12

Identification of manufacturer or distributor of dispensed drug product on prescription

Sec. 12. The pharmacist shall record on the prescription in writing or in an electronic format for an electronically transmitted prescription the name of the manufacturer or distributor, or both, of the actual drug product dispensed under this chapter.

As added by P.L.2-1993, SEC.25. Amended by P.L.204-2005, SEC.13.